005_510(k) Summary

DEC 2 1 2012

A. Manufacturer - and Contact Information

Manufacturer: IMDS Operations B.V.
Ceintuurbaan Noord 150
9301 NZ Roden
The Netherlands
Telephone: +31 50 8200 230
Fax: +31 50 8200 231

Contact Person: Mr. E. Schulting
Managing Director
Telephone: +31 50 8200 230
e-mail: eschulting@imds.nl

Date of preparation: 04 April 2012

B. Reason for Premarket Notification

This Premarket Notification is being submitted for the NHancer™ guidewire support catheter which is a new device being manufactured by IMDS Operations B.V.

C. Device Information

Trade Name: NHancer™

Common Name: 0.014" guidewire support catheter

Classification Name: Percutaneous Catheter (21 CFR 870.1250, product Code DQY)

D. Device Description

The purpose of the NHancer™ guidewire support catheter is to facilitate the placement of a guide wire through an occluded vessel during Percutane Transluminal Coronary Intervention procedures. The NHancer™ is a single use device, consisting of a shaft, a distal tip and a female luer (hub) on the proximal end. On the shaft are two depth markings applied to indicate the length of the part of the device that is in the body. On the distal tip of the device a radiopaque marker band is applied. The distal part of the shaft is fitted with a hydrophilic coating. On the shaft a torquer is placed. With this component the catheter can be locked on to the guide wire that is in the device. The torquer is initially placed on a strain relief which is located on the proximal end of the shaft, near the female luer (hub).

005_510(k) Summary (continued)

E. Intended Use

The IMDS NHancer™ Guide Wire Support Catheter with Hydrophilic Coating is a guidewire exchange and infusion device designed for use in the vascular system. The IMDS NHancer™ guidewire support catheter is intended to support a guidewire during access of vasculature and allows for exchange of guidewires and provides a conduit for the delivery of diagnostic contrast agents.

F. Principle of Operation / Technology

The NHancer™ guidewire support catheter is operated manually or by manual process.

During an interventional procedure, the physician will follow the standard procedure of placing a guide wire and introducer within a vessel. Then a guiding catheter or sheath would be advanced over the guide wire. Next, the NHancer™ guidewire support catheter would be inserted over the guide wire and through the hemostasis valve of the guiding catheter or sheath. The guide wire and NHancer™ guidewire support catheter would then be advanced to the target vessel. The NHancer™ guidewire support catheter can then be used for support and exchange of guide wires or for injection of contrast media.

G. Statement of Equivalence

The NHancer™ guidewire support catheter submitted in this 510(k) is substantially equivalent in intended use, design, technology, principles of operation, materials and performance to the Spectranetics QuickCross® Support Catheters, cleared under K033678.

005_510(k) Summary (continued)

H. Design / Materials / Specifications

The NHancer™ guidewire support catheter in this submission uses a similar design, similar materials and specifications as the predicate device: Spectranetics QuickCross® Support Catheter. Differences in design, materials and/or specifications between the devices do not raise any issues of safety and effectiveness. Below is a table with a comparison of the design, materials and specifications between the NHancer™ guidewire support catheter and the predicate devices.

#	Item	Predicate Device: Spectranetics QuickCross Support Catheter Model Number: 518-032	IMDS NHancer™ guidewire support catheter Model Number: 8101-B140P
1	Design / construction	OTW, single lumen	OTW, single lumen
2	Shaft material	Polyethylene	Pebax / Polyethylene
3	Strain Relief	present	present
4	Luer Lock or Hub	Female, 6% taper and screw conform ISO 594-1 and -2.	Female, 6% taper and screw conform ISO 594-1 and -2.
4	Number of radiopaque markers	3	1
6	Radiopaque marker material	Platinum	Platinum / Irridium
7	Effective Length or Usable Length	135 cm	140 cm
8	Exit Marker location	none	95 and 105 cm
9	Guide wire compatibility	0.014 inch	0.014 inch
10	Maximum injection pressure	300 psi	300 psi
11	Outer Diameter Shaft	0.76 mm	0.75 mm
12	Minimum Guiding Catheter	5 Fr	5 Fr
13	Tip design / shape	Straight	Straight
14	Hydrophilic coating length	Distal 40 cm	Distal 25 cm
15	Hydrophilic coating material	not known	PU / PVP hydrophilic coating

005_510(k) Summary (continued)

I. Performance

The NHancer™ guidewire support catheter in this submission and the Spectranetics QuickCross® Support Catheter, cleared under K033678, have similar performance characteristics. The following performance tests were conducted on these catheters. Comparison testing was performed on the IMDS NHancer™ guidewire support catheter and the Spectranetics QuickCross Support Catheter.

1) Crossability (both in-vitro as well as in-vivo)
2) Guide wire friction (in-vitro)
3) Guidewire Torqueability (both in-vitro as well as in-vivo)
4) Flow rate (in-vitro)
5) Marker visibility (in-vivo)
6) Guidewire exchangeability (in-vivo)
7) Contrast medium administration (in-vivo)

The performance of the NHancer™ guidewire support catheter is substantially equivalent to the performance of the predicate device (Spectranetics QuickCross® Support Catheter). The performance of the NHancer™ guidewire support catheter met all the acceptance criteria.

In addition, the following bench tests were performed on NHancer™ guidewire support catheter to assure proper performance. All test results met the acceptance criteria.

1) Usable length
2) Length of coated part
3) Tip inner diameter
4) Tip length
5) Outer diameter
6) Pull strength after 5 rotations
7) Burst strength after 5 rotations
8) Flow rate testing
9) System Burst testing
10) 6% taper Luer testing
11) Screw connection Luer testing
12) Female Hub
13) Exit marker location
14) Radiopaque marker location
15) Visual appearance
16) Force at break: shaft
17) Force at break: shaft/hub connection
18) Force at break: tip/shaft connection
19) Outer diameter radiopaque marker
20) Dimensions of packaging box
21) Product integrity after simulated transportation test
22) Pouch bubble test
23) Liquid dye test
24) Pouch seal strength
25) Pouch seal width
26) Label adhesive retention
27) Legibility of product information
28) Pouch delamination assessment after opening
29) Kink resistance
30) Torque testing
31) Coating Integrity and Particulate Evaluation

005_510(k) Summary (continued)

J. Additional Safety Information

Biocompatibility testing was performed in accordance with the Blue Book Memorandum, G95-1, Use of International Standard ISO 10993, and Biological Evaluation of Medical Devices part 1: Evaluation and Testing. The NHancer™ guidewire support catheter is classified as an externally communication device, circulating blood, limited contact (up to 24 hrs), which resulted in the following tests:

1) Thrombosis testing
2) Hemolysis testing
3) Cytotoxicity (Growth Inhibition test)
4) Irritation (Intracutaneous Reactivity)
5) Sensitation (Local Lymph Node Assy)
6) Systemic Toxicity (Acute Systemic Toxicity)

The NHancer™ guidewire support catheter successfully passed all above listed biocompatibility tests.

The NHancer™ guidewire support catheter is sterilized by means of irradiation (gamma irradiation). The sterility has been validated in accordance with the applicable parts of the ISO 11137 standard (part 1: 2006, part 2: 2006) and ISO 11737 standard (part 1: 2006, part 2: 2009) to provide a Sterility Assurance Level (SAL) of 10^{-6}.

The NHancer™ guidewire support catheter is certified to be non-pyrogenic in the unopened and undamaged package. An Endotoxin Kinetic Turbidimetric test has been performed and will be performed for future production batches in accordance with current Ph. Eur. Chapter 2.6.14 Method C, kinetic turbidimetric test, as well as current USP, the harmonized part of chapter 85 and chapter 161. Initial production batches of the NHancer™ guidewire support catheter successfully passed the Endotoxin Turbidimetric test.

K. Substantial Equivalence

The NHancer™ guidewire support catheter submitted in this 510(k) is substantially equivalent in the general intended use, design, materials, specifications, principles of operation / technology, and performance to the Spectranetics QuickCross Support Catheter cleared under K033678. Differences between the devices do not raise any issue of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

IMDS Operations B.V.
c/o Mr. E. Schulting
Managing Director
Ceintuurbann Noord 150
9301 NZ Roden
The Netherlands

DEC 2 1 2012

Re: K121077
Trade/Device Name: NHancer guidewire support catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 22, 2012
Received: November 26, 2012

Dear Mr. Schulting:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

004_Indications for Use Statement

510(k) Number (if known): K121077

Device Name: NHancer (model number: 8101-B140P)

Indications For Use:

The IMDS NHancer™ Guide Wire Support Catheter with Hydrophilic Coating is a guidewire exchange and infusion device designed for use in the vascular system. The IMDS NHancer™ guidewire support catheter is intended to support a guidewire during access of vasculature and allows for exchange of guidewires and provides a conduit for the delivery of diagnostic contrast agents.

Prescription Use _X_ **AND/OR** **Over-The-Counter Use _N/A_**

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121077